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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/709,829

11/10/2000

James J. Fort

6488.US.02

3590

23492

7590

04/16/2007

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/709,829

Applicant(s)

FORT ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-36 and 39-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-47 and 49-51 is/are allowed.
- 6) ☒ Claim(s) 30-36 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 48 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 20070219.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

1. The amendment filed February 19, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to the paragraphs beginning at page 8, line 6, and at page 8, line 18, of the specification constitute new matter. The amendments broaden the disclosure of the specification, i.e. from a disclosure in which the dispersions are limited to molecular dispersions, to a disclosure in which molecular dispersions are only an example of the dispersions. With respect to MPEP 2163.07, there is no "obvious" error in the specification as originally filed which needs to be corrected. Applicants are free to be their own lexicographers, and the possible existence in the prior art of alternative definitions of "solid dispersion" does not mean that Applicants' original definition was incorrect. Applicants have not explained what examples of solid dispersions given by the Chiou et al article are not embraced by the specification as originally filed, which examples would be embraced by the amended specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

2. Claims 30-36 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of "markedly improved", as recited in instant claim 30, is unclear. The term is not defined in the specification, and does not appear to have an art-recognized definition. The term is used in Example 1, in conjunction with Figure 1. However, it is not clear if the degree of improvement required by the claim terminology is limited to the degree of improvement shown in Figure 1, or if the degree of improvement shown

Art Unit: 1654

in Figure 1 is merely exemplary. If the latter interpretation is intended, then it is not clear how to determine whether a particular degree of improvement in dissolution rate is “markedly” improved or not and thereby embraced within the scope of the claim.

3. Claims 30-36, 39-42, 48, and 52 are objected to because of the following informalities:

At claim 30, line 3, “the” should be inserted after “wherein”, and “a” should be inserted after “has”. At claim 48, line 2, a beginning parenthesis is missing from before “2S”. Appropriate correction is required.

4. Applicant's amendments and arguments and the declaration filed February 19, 2007 have been fully considered and are persuasive with respect to the objections and rejections set forth in the previous Office action.

The prior art rejections based upon Al-Razzak et al (U.S. Patent No. 5,610,193) as the primary reference are withdrawn. The declaration under 37 CFR 1.132 by Law, filed February 19, 2007 shows that the ritonavir used by Al-Razzak et al was in crystalline form, and shows that the ritonavir would not have been expected to be converted into amorphous form when forming the composition of Al-Razzak et al's Example 4. Al-Razzak et al do not teach or suggest Applicants' claim limitations requiring an amorphous form of ritonavir.

5. Claims 43-47 and 49-51 are allowed. Claims 30-36 and 39-42 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action. Claims 48 and 52 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action.

Art Unit: 1654

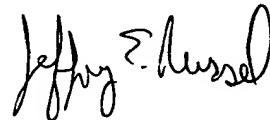
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
April 6, 2007